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09/347,845	09/30/1999	YI YANG	243/079	4401

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EXAMINER

BUI, VY Q

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/347,845

Applicant(s)

YANG ET AL.

Examiner

Vy Q. Bui

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3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-15 and 17-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 3-4, 8-15, 17-22 and 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by VON OEPEN (6,193,747).

As to claims 1, 3-4, 8-11, and 24-25, VON OEPEN (Fig. 8 as reproduced and shown on **page 5** of this paper and see column 1, lines 36-39, VON OEPEN) discloses a **non-sinusoidal** zigzag pattern tubular stent (60) expandable from a contracted condition for easy introduction of the stent into a body lumen (a blood vessel) to an enlarged condition for supporting and keeping the body lumen (the blood vessel) open. Inherently, the stent is biased from a contracted condition either by a balloon or by a self-expanding property of the stent material towards an enlarged condition (as recited in claims 4, 24-25) to support the body lumen. The stent comprises:

- **A central portion consists essentially of a series of cylindrical bands, each band comprises a generally non-sinusoidal zigzag pattern of diagonal elements having generally arcuate shapes, arbitrarily assigned either a clockwise or counter clockwise orientation. Notice that the central portion consists essentially**

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of a series of cylindrical bands because the central portion includes a majority of cylindrical bands .

- A plurality of straight and short or long connectors (I-shaped labeled as elements 66, 67) extending substantially parallel to the longitudinal axis of the stent. Notice that in a contracted configuration during deployment of the stent, connectors 66, 67 are squeezed closed one to each other and connectors 66, 67 are substantially parallel to the longitudinal axis of the stent.
- The short longitudinal connectors have a longitudinal dimension substantially smaller than a longitudinal dimension of the diagonal elements (as recited in claim 9). The diagonal elements comprise 1<sup>st</sup> and 2<sup>nd</sup> generally straight portions having 1<sup>st</sup> ends connected to preceding and succeeding diagonal elements and 2<sup>nd</sup> ends being connected together (as recited in claim 10).
- The diagonal elements of each cylindrical band are out of phase with any adjacent cylindrical band (as recited in claim 11).

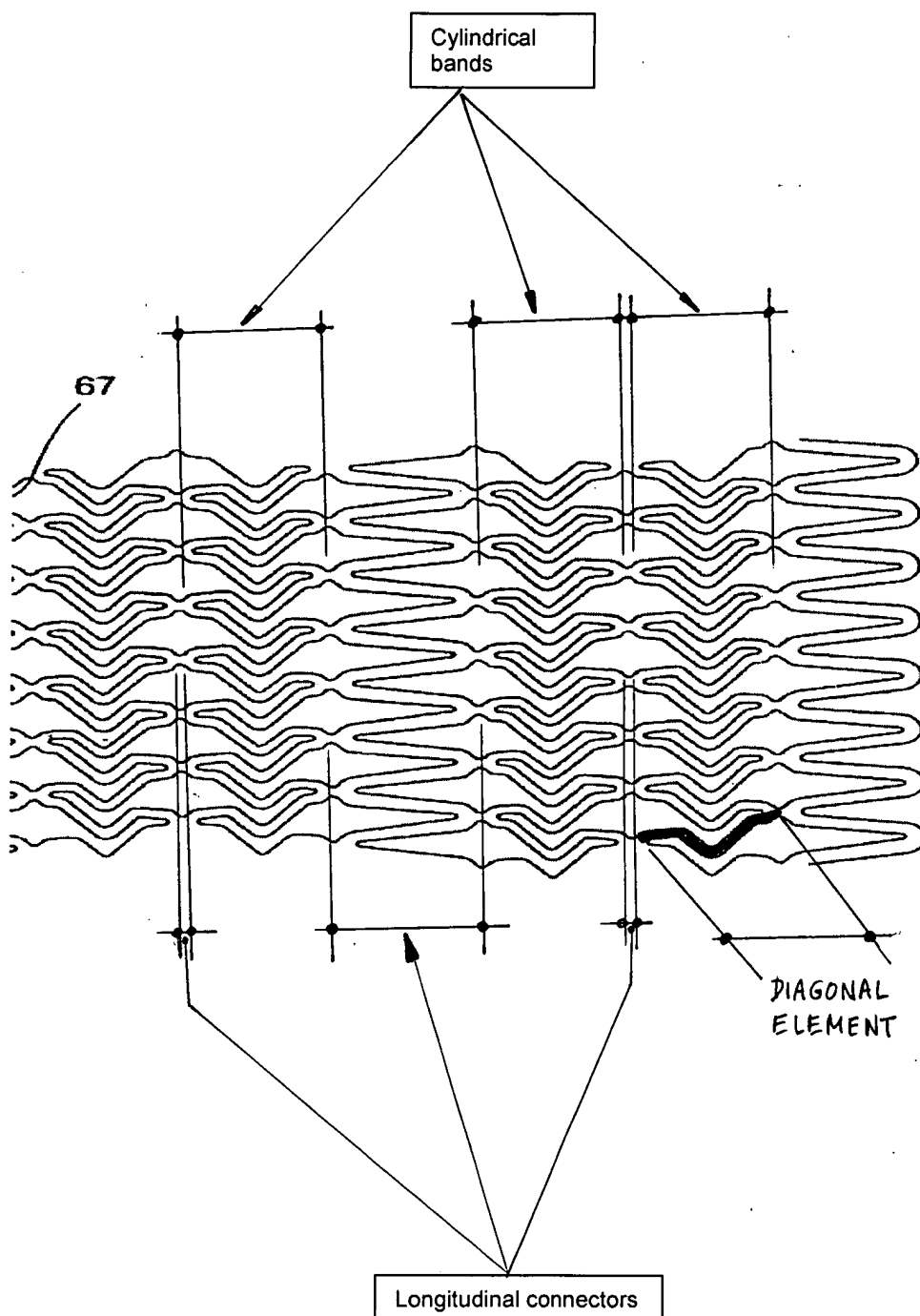
As to claims 12-15 and 17-22, VON OEPEN (Fig. 8 as reproduced and shown on **page 6** of this paper; see column 1, lines 36-39, VON OEPEN) discloses a tubular stent (60) comprising:

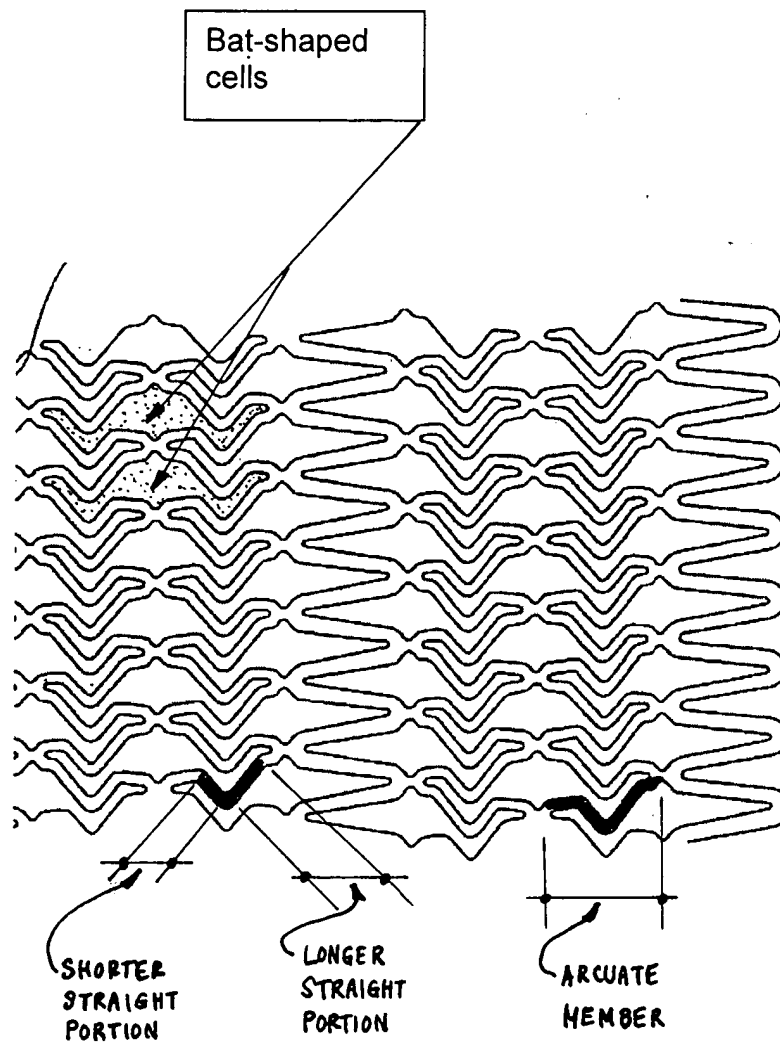
- A central portion consist essentially of a plurality of bat-shaped cells formed from **non-sinusoidal** cylindrical bands each cell having a head region, a tail region and opposing curved wing regions. The central portion consists essentially of a plurality of bat-shaped cells because there are a majority of bat-shaped cells in the central portion.
- A plurality of **straight short and long** connectors (I-shaped) extending substantially parallel to a longitudinal axis (as recited in claims 12 and 15) and

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connecting each of the adjacent cells. Notice that in a contracted configuration during deployment of the stent along a blood vessel, connectors 66, 67 are squeezed closed one to each other and connectors 66, 67 are substantially parallel to the longitudinal axis of the stent.

- The head and tail regions are aligned about the circumference of the stent, the wing regions have a generally V-shaped extending longitudinally away from the head and tail regions (as recited in claim 13).
- The cells are arranged sequentially about the circumference, thereby defining a cylindrical band (as recited in claim 14).
- The wing regions are defined by 1<sup>st</sup> and 2<sup>nd</sup> arcuate members, the 1<sup>st</sup> and 2<sup>nd</sup> arcuate members comprising a pair of generally straight portions connected to one another by a curved portion, and the curved portion defines an apex of the "V" shape curved wing regions, the apices all pointing substantially in a single direction (as recited in claims 17-18).
- The head regions and tail regions are defined by longitudinal connectors (I-shaped connectors), one of the straight portions of each of the first and second arcuate members is substantially shorter than the other generally straight portion of the respective arcuate member, and the longitudinal connectors define the tail region also define the head region of an adjacent cell (as recited in claims 19-21).
- The connectors comprise a longitudinal connector (V-shaped connector) extending between a wing region of a first cell and a wing region of an adjacent cell (as recited in claim 22).





***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over VON OEPEN (6,193,747) in view of STEINKE (6,224,626).

As to claims 2 and 23, VON OEPEN discloses substantially all structural limitations as recited in the claims, except for the stent 60 is not a coiled-sheet stent. STEINKE (column 2, lines 15-19; claim 6) discloses a coiled sheet stent of a shape memory material such as Nitinol having a variable expanded diameter to better fit inside a blood vessel over a tubular stent, which can better fit in a blood vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make VON OEPEN stent 60 a coiled-sheet stent as claimed as this configuration would provide a stent with variable expanded diameter to better fit inside a blood vessel.

3. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over VON OEPEN (6,193,747) in view of STEINKE (6,224,626) and further in view of KHOSRAVI et al (5,824,054).

As to claims 5-6, VON OEPEN (Figs. 8-9, 4-6) discloses substantially all structural limitations as recited in the claims, including ends of adjacent diagonal are expanded further away from one another in a stretched condition than in an unstretched condition. VON OEPEN and STEINKE do not disclose the stent made of a shape memory alloy having a transition temperature below the body temperature. However, KHOSRAVI (column 5, lines 59-63) discloses a coiled sheet stent made of a shape memory alloy having a transition temperature below body temperature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the VON OEPEN stent a coiled-sheet stent of a shape memory alloy having a transition temperature below body temperature as taught by KHOSRAVI, as this modification



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would allow the stent to be expanded by the body temperature of a patient when deployed.

***Response to Amendment***

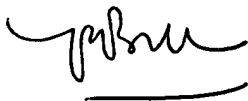
The claims as filed in the amendment on 9/15/2003 (paper 16) under 37 CFR 1.131 has been carefully considered. However, the claims have not overcome the VON OEPEN reference as indicated in the above rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB

November 2, 2003.